PRODUCT PERFORMANCE / EFFICACY REVIEW

Mark Suarez, Entomologist - IB

Mark C. Suarez 5 August 2008

DATE:	5 August 2008
EPA REG. NUMBER:	239-EAOL
PRODUCT NAME:	Home Defense Max Perimeter Insect Killer Aerosol (1)
REGISTRANT:	The Ortho Business Group
PM:	George LaRocca, PM13
REVIEWER:	Dana Pilitt
DECISION #.:	388043
DP BARCODE:	352665
ACTION:	R310
ACTIVE INGREDIENT(S):	128825, Bifenthrin.....0.05% 128722, Prallethrin.....0.03%
TYPE:	RTU Aerosol
OPPTS GUIDELINE(S):	810.3500

MRID:			
	47311109	Submitted	GLP? No.
	45060601	Cited	
	46553201	Cited	

SITES: In and around residential and commercial areas as a space, area or contact spray

PESTS: Ants, Roaches, Scorpions, Spiders, Centipedes, Fleas, Flies, Mosquitoes, Ticks

STUDY APPLICATION RATE: "Until slightly wet without soaking"

LABEL APPLICATION RATE: Spray until surfaces are wet

STUDY SUMMARIES

MRID 47311209. McDonald, C. (2006) Evaluation of Residual Efficacy of Ortho Home Defense Indoor & Outdoor Insect Killer Against Multiple Arthropod Pests. Project Number: 05OH131O02. Unpublished study prepared by Scotts Company. 10 p.

The data submitted in MRID 47311109 were generated in a laboratory study designed to assess the efficaciousness of a 0.05% bifenthrin product [EPA Reg. No. 239-2663] against harvester ants (*Pogonomyrmex badius*), carpenter ants (*Camponotus pennsylvanicus*), red imported fire ants (*Solenopsis invicta*), striped tail scorpion (*Vaejovis spinigerus*), and the dune scorpion (*Smeringurus mesaensis*) more than one year after application to surfaces stored under laboratory conditions. The product was tested when applied to vinyl or ceramic tiles and polypropylene surfaces. Four replicates of each ant/surface combination were run. Five replicates were run for each scorpion/surface combination. The same numbers of replicates of control arthropods were maintained on untreated surfaces. Arthropods were confined to the treated surfaces for 24 hours. Mortality was recorded at 24, 48, and 96 hour after exposure. Control mortality was within acceptable parameters.

Organism	Surface	Number of Arthropods /Replicate	Exposure Interval (DAT)	Mortality (%)
Harvester Ant	Vinyl Tile	10	541	97.4
	Polypropylene	10	539	94.7
Carpenter Ant	Vinyl Tile	5	428	94.1
	Polypropylene	5	421	100
Red Imported Fire Ant	Vinyl Tile	10	533	90.6
	Polypropylene	10	526	100
Striped Tail Scorpion	Ceramic Tile	1	416	100
	Polypropylene	1	416	100
Dune Scorpion	Ceramic Tile	1	430	100
	Polypropylene	1	429	100

TABLE 1. Residual efficacy of 0.05% bifenthrin formulation against arthropods when applied to different surface types. There were five replicates per arthropod by surface combination.

The data submitted demonstrate the efficaciousness of the product against the target arthropods when applied to non-porous surfaces organisms are forced to contact for a great deal of time. The main deficiencies noted are that the exposure interval is unreasonably long and no porous surfaces were tested.

Per the efficacy review of 2 November 2005, "Increasing the length of residual claims for other pests of public health importance will require the submission of corroborative data from a study conducted under normal use conditions (including, but not limited to light exposure, surface types, application rate, exposure duration, etc...). The length of residual claims on the label may not be modified for the following insects currently listed on the product label:..."

The data submitted fail to fulfill the stated obligation. Specifically, the exposure duration is unreasonable and the surface types tested do not reflect those commonly present when the product is used as labeled.

MRID 46553201. McDonald, C. (2003) Evaluation of Residual Efficacy of Ortho Home Defense Indoor & Outdoor Insect Killer (EPA Reg. No. 239-2663) Against Multiple Arthropod Pests. Project Number: 02OH211O01. Unpublished study prepared by The Scotts Company. 8 p.

See attached review. Data intended to support 12 month residual claims. Data were to be corroborated according to 2 November 2005 DER and registration letter dated 9 November 2005. Confirmatory data have not been submitted in association with the product [EPA Reg. No. 239-2663].

MRID 45060601. Levey, C. (2000) Evaluation of Knockdown Speed and Mortality Efficacy on the Hobo Spider: Ortho Home Defense Indoor & Outdoor Insect Killers: Lab Project Number: 481001. Unpublished study prepared by Scotts Northeast Research Center. 8 p.

See attached review. Data found to support claims against Hobo spiders.

ENTOMOLOGIST'S COMMENTS AND RECOMMENDATIONS:

The data submitted do not support claims against the desired pests for public health concern. Also, the 12 month residual claims have not been supported. Remove both all pests of public health concern (carpenter, fire, pharaoh, and harvester ants, roaches, scorpions, black widow and brown recluse spiders, centipedes, fleas, flies, mosquitoes, and ticks) and all residual claims from the label.

The product label may retain general contact kill claims against pests NOT of public health concern.

Claims addressed individually (remove or modify, as indicated):

~~1. Keeps bugs out all year!* *12 month control indoors for Ants (excluding fire, pharaoh, and carpenter), Crickets, Scorpions, and Spiders (excluding black widow and brown recluse).~~

~~2. Creates a bug barrier~~

3. www.homedefensemax.com – must include standard disclaimer, as the website is considered collateral labeling.

4. For best results, it may be necessary to re-apply every six months ~~in high traffic and high sunlight areas~~. *Modify this claim to read "re-apply every [x amount of time]" no more frequently than permitted according to the risk assessment.*

5. Marketing Claims:
   a. **Knockdown claims:**
      - ~~Fast acting~~
      - ~~Quick knockdown~~
      - ~~Fast knockdown~~
      - ~~Kills bugs in seconds~~
      - ~~Kills (bugs) fast~~
      - ~~Starts killing in seconds~~
      - ~~Kills on contact [Guaranteed]~~
   b. **Water based product claims:**
      - Water based
      - Dries clean
      - Dries fast
      - No oily residue
      - No mess
      - Does not stain (fabrics, floors, wood, surfaces)
      - Non-staining
      - Unscented
      - Fragrance-Free
      - Leaves no odor
      - No sticky mess
      - No lingering odor
      - Odor Free
      - Odorless
      - No greasy residue (mess)
      - Continuous (aerosol) spray
   c. **Residual Control claims:**
      - ~~Keeps bugs out all year!* * for listed insects (* 12 month control on Ants (excluding Fire, Pharaohs, and Carpenter), Crickets, Scorpions and Spiders (excluding Black Widow and Brown Recluse)~~
      - ~~Up to 12 month control indoors* *for listed insects~~
      - ~~Provides year long control indoors* *for listed insects~~
      - ~~Up to 12 month (one year) control indoors for listed insects~~
      - ~~Up to 12 month (one year) control indoors for listed insects: crickets, ants (including harvester ants), spiders and scorpions~~
      - ~~Kills Two (2) ways: 1) Kills insects fast (on contact) and 2) It keeps killing with residual action even after you spray, for up to 12 months inside (* *for listed pests) (for listed pests)~~
      - ~~Long-lasting insect protection (control)~~
      - ~~Now up to 12 month indoor control*~~
      - ~~One application provides year-long control indoors of listed insects~~
      - ~~Protects against home-invading insects all year long* *for listed insects~~

- ~~Year-long indoor insect protection* * for listed insects~~
- ~~Keeps killing all year* * for listed insects~~
- ~~Kills on contact, keeps on killing for up to 12 months inside* *for listed insects~~
- ~~Kills bugs inside (indoors). Keeps bugs outside (out) (all year* * for listed insects) (long)~~
- ~~Kills the bugs you have and prevents new bugs (from coming inside) (from coming in) (all year long* *for listed insects)~~

d. **Barrier-related claims:**

- ~~Kills all major home invading insects (with a bug barrier)~~
- ~~Kills home invading pestslinsects (with a bug barrier)~~
- ~~Creates a barrier that will kill the bugs you have and prevent new bugs from coming in all year* *for listed insects~~
- ~~(New) Barrier Technology stays put (lasts) (keeps killing bugs) for 12 months* (an entire year*) *for listed insects~~
- ~~(New) Barrier Technology~~
- ~~Protect(s) your home from bugs~~
- ~~Protect(s) your family from (home-invading) insects (bugs)~~
- ~~Immediately forms (creates) (establishes) a (bug) (insect) barrier~~
- ~~Kills and prevents (insects) (inside your home) (outside your home)~~
- ~~Kills bugs inside. Keeps bugs out(side)~~
- ~~Protect against (invading) bugs~~
- ~~Provides protection against home invading insects~~
- ~~Spray around entire inside of your home to create a bug barrier~~
- ~~Barrier protection~~
- ~~Keeps on killing with residual action, even after you spray~~
- ~~Use in garages, basements, attics to keep bugslinsects from coming into (entering) your~~
- ~~home.~~
- ~~Use with confidence in garages and/or basements and/or attics.~~
- ~~Guards against bugs so you don't have to~~
- ~~Guards against the bugs you can't (don't) see~~
- ~~Keeps on killing after spray has dried~~

e. **Area-related claims:**

- ~~16 oz treats (covers) 1-51 linear feet~~
- ~~16.5 oz treats (covers) 156 linear feet~~
- ~~17 oz treats (covers) 161 linear feet~~
- ~~17.5 oz treats (covers) 166 linear feet~~
- ~~18 oz treats (covers) 170 linear feet~~
- ~~18.5 oz treats (covers) 175 linear feet~~
- ~~19 oz treats (covers) 180 linear feet~~
- ~~Treats (1-42) (1-46) (1-51) (1-56) (1-61) 166 (1-70) (1-75) (1-80) linear feet!~~
- ~~Treats the average 1800 sq. ft. home one time!~~

- ~~Enough to create an (one) entire bug barrier (treatment) for the average 1800 sq. ft. home!~~
- ~~Treats (1-61) 166 linear feet (1-70) (1-75) (1-80) enough to create an entire bug barrier for the average 1800 sq. ft. home!~~
- Consistent spray for maximum accuracy
- Consistent/even coverage
- Ideal for small areas
- Use inside and outside your home!

f. **Where to use/How to use claims**

- Apply along (and behind) baseboards
- Apply along (and behind) appliances
- Apply beneath (and behind) sinks
- Apply in other areas where insects are often
- Gets into cracks and crevices
- Gets to the places bugs hide
- Reaches where bugs hide
- Ready to Use
- You're (It's) always ready to spray
- Easy to use
- The easy way to spray (Home Defense Max)
- Stays where you spray it
- Change the way you spray
- ~~Targeted bug control (kill)~~
- ~~Targets bugs in tight places~~
- Use (Can be used) in (bathrooms), (kitchens), (family rooms), (pantry) and (bedrooms)
- ~~Works on all listed surfaces~~

g. **Other claims**

- Guaranteed (results)
- ~~Kills ants and roaches (and many other listed pests)!~~
- ~~Kills roaches, ants, fleas, flies, mosquitoes, Brown dog ticks, spiders, earwigs, silverfish, and other listed insects.~~
- No more tired hands
- No more hand fatigue
- Precise control for maximum accuracy
- Broad spectrum

Enclosure
000239-0EAOL S831942-ER

PRODUCT PERFORMANCE / EFFICACY REVIEW

Mark Suarez, Entomologist - IB

DATE:	2 November 2005
EPA REG. NUMBER:	269-2668
PRODUCT NAME:	Ortho Homedefense Indoor & Outdoor Insect Killer
REGISTRANT:	The Ortho Business Group
PM:	George LaRocca, PM 13
REVIEWER:	BeWanda Alexander
DECISION #:	357464
DP BARCODE:	318491
ACTION:	R34
ACTIVE INGREDIENT(S):	128825, Bifenthrin.....0.05%
TYPE:	Liquid, RTU
OPPTS GUIDELINE(S):	810.1000 810.3000 810.3500
MRID:	46553201
GLP ?:	No.
SITES:	Indoor Residential
PESTS:	Crickets, ants (including harvester ants), spiders, scorpions
STUDY APPLICATION RATE:	"to achieve good coverage"
LABEL APPLICATION RATE:	"until slightly wet without soaking"

STUDY SUMMARIES:

MRID 46553201. *McDonald, C. (2003) Evaluation of Residual Efficacy of Ortho Home Defense Indoor & Outdoor Insect Killer (EPA Reg. No. 239-2663) Against Multiple Arthropod Pests. 8p.*

The submitted study tested the residual activity of the subject formulation. Polypropylene containers were treated "to achieve good coverage" and stored in the laboratory "under ambient conditions". No information was presented regarding the exposure of treated containers to light. The efficacy demonstrated against crickets (*Acheta domesticus*), Western Harvester Ants (*Pogonomyrmex occidentalis*), Wolf Spiders (*Lysoca* spp.), and Striped-Tail Scorpions (*Vejovis spinigerus*) was recorded (Table 1). The exposure interval was not clearly presented, but appears to have been approximately 24 hours (Based upon information provided on the raw data sheets.) For each arthropod three replicates were run for both the treatment group and the control. The experimental protocol for control arthropods was not described.

Arthropod	Number of Individuals/Replicate	Months after Treatment	% Mortality
Harvester Ant	10	18	100
Striped-Tail Scorpion	1	18	100
Wolf Spider	1	19	100
Cricket	5	20	100

Table 1. Efficacy of treated polypropylene containers against arthropod species, time since treatment, and mean mortality observed.

ENTOMOLOGIST'S COMMENTS AND RECOMMENDATIONS:

The data submitted indicate that the formulation when applied to polypropylene surfaces can be efficacious for greater than the 12 month claim requested. The product was, without variability, entirely efficacious against the organisms tested. However, the level of detail provided in the study precludes determination of the effectiveness of the formulation under actual field conditions.

In the future, data should be submitted with an explicit description of the experimental procedure that permits proper evaluation of the study (e.g., quantitative application rate, complete description of trial conditions [quantitative light and temperature measurements], description of control animal treatment, etc...). The registrant is encouraged to discuss or submit protocols to the Agency for review prior to study initiation.

Recommendations:

1. Based upon the data submitted, 12 month residual claims for indoor and pantry application of the formulation are acceptable for the following arthropods:
    a. Spiders (with the exception of Black Widow and Brown Recluse Spiders)
    b. Crickets

2. Based upon the data submitted, 12 month residual claims for indoor and pantry application of the formulation are conditionally acceptable for the following arthropods:
    a. Ants (excluding Fire, Pharaoh's, and Carpenter Ants)
    b. Scorpions

The addition of the pests above is conditional based upon the submission of corroborative data, based upon studies as described below in #3, within one year.

3. Increasing the length of residual claims for other pests of public health importance will require the submission of corroborative data from a study conducted under normal use conditions (including, but not limited to light exposure, surface types, application rate, exposure duration, etc...). The length of residual claims on the label may not be modified for the following insects currently listed on the product label:
    a. Black Widow Spider
    b. Brown Recluse Spider
    c. Carpenter Ants
    d. Centipedes
    e. Foraging Fire Ants
    f. Fleas
    g. Flies
    h. Houseflies
    i. Mosquitoes
    j. Roaches
    k. Ticks (including ticks that *may* transmit Lyme Disease)

Enclosure
000239-02663 S779318-ER

EFFICACY REVIEW

DATE: IN 3-31-00 OUT 5-23-00

FILE OR REG. NO. 239-2663

PETITION OR EXP. PERMIT NO.

DATE DIV. RECEIVED March 7, 2000

DATE OF SUBMISSION February 28, 2000

DATE SUBMISSION ACCEPTED

TYPE PRODUCT(S): (I,)D, H, F, N, R, S

DATA ACCESSION NO(S). 450606-01;D264640;S577704;Case#063288;AC:306

PRODUCT MGR. NO. 03-Layne/Keigwin

PRODUCT NAME(S) Home Defense® Indoor & Outdoor Insect Killer

COMPANY NAME The Scotts Company d/b/a The ORTHO Group

SUBMISSION PURPOSE Provide performance data in support of adding a claim for control of an additional public health pest, the hobo spider, to the existing label.

CHEMICAL & FORMULATION Bifenthrin* 0.05%
*Cis/trans isomer ratio: (8.32 lbs./gal. ready-to-use liquid soln)
Minimum 97% cis, maximum 3% trans

CONCLUSIONS & RECOMMENDATIONS The data presented in EPA Accession (MRID) Number 450606-01, having been obtained from a standard laboratory test conducted according to the requirements of § 95-11, subparts (b)(1) through (4), (6) and (7) on p. 268 and meeting the standard of § 95-11(c)(2)(ii)(A)(a) on p. 270 of the Product Performance Guidelines, are adequate to demonstrate the ability of the subject product to produce 100% knockdown of the hobo spider in 5 minutes when applied as a topical spray of approximately 2.0 gms or 1.0 mg active bifenthrin, which resulted in 100% mortality at 24 hours. Thus, the additional claims for hobo spider in the lists of pests controlled on indoor and outdoor home surfaces on p. 4 of the draft proposed labeling and of nuisance pests indoors and outdoors on p. 5 of the draft proposed labeling, are acceptable.

RL Vern L. McFarland, IB